IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant(s): Gerald Horn
Appl. No.: 09/854,414
Conf. No.: 7675
Filed: May 10, 2001
Title: OPHTHALMIC FORMULATIONS
Art Unit: 1618
Examiner: Z. Ray
Docket No.: 114309-1007

Mail Stop Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

AFFIDAVIT OF GERALD HORN, M.D.

I, Gerald Horn, hereby states as follows:

1. I am the sole inventor of the above-referenced U.S. Patent Application No. 09/854,414.

2. I have reviewed the Final Office Action issued on September 11, 2007 regarding this case, a copy of which is attached herewith as Exhibit A. In particular, I have reviewed U.S. Patent No. 4,443,441 (Galin) as referenced in the Final Office Action on page 2, a copy of which is attached herewith as Exhibit B.

3. Of the presently pending claims, claim 74 is the sole independent claim. Claim 74 is directed to an ophthalmic, night vision formulation. The formulation includes a sterile aqueous carrier; and a pharmaceutically active compound consisting essentially of phentolamine in a therapeutically effective amount so as to effectively disrupt endogenous compounds which stimulate dilator muscles of a human eye thereby effectively reducing pupil size to improve night vision.

4. The claimed phentolamine-based formulation inhibits pupillary dilation in scotopic conditions preferentially over constriction of the pupil, affecting the dilator muscles of the iris preferentially, and has no clinically significant effect on the ciliary muscle responsible for accommodation. Therefore, pupil size is optimized to obtain enhanced vision acuity in dim light (e.g., at night) by reducing the pupil diameter in dim light. Moreover, this result was unexpected

since conventional ophthalmology indicated that reducing pupil size in dim light would cau vision acuity to deteriorate.

5. I also conducted experiments that demonstrated the beneficial effects of t phentolamine-based formulation as claimed. For example, Table 1 on page 27 of the prese application indicates that the phentolamine-based formulation demonstrates enhanced pup reduction effect while minimizing eye redness as compared to other types of alpha-1 antagoni based formulations. Further, Table 2 on page 28 of the present application demonstrates th beneficial effects on night vision by reducing the pupil diameter in dim light. In Table 2, th glare and halo effects were reduced in addition to an improvement in depth perception b reducing the pupil diameter in dim light.

6. In contrast, Galin is directed to the use of alpha adrenergic blocking agents to a in the fixation of intraocular lenses. See, Galin, col. 1, lines 4-5. Indeed, Galin further disclos that this type of pupillary activity can reduce eccentric synechia formation and lens dislocatio See, Galin, column 1, line 61-67. Nowhere does Galin suggest that the reduction of pupil size dim light can enhance night vision in contrast to the claimed phentolamine-based formulatio Again, the reduction of pupil size to enhance night vision was contrary to convention ophthalmology as previously discussed. Moreover, nowhere does Galin suggest that phentolamine-based formulation has enhanced effects on pupil reduction in dim light, thu enhancing night vision, as compared to other types of formulations. Indeed, the only workin example in Galin relates to a thymoxamine-based formulation to aid in the fixation of a intraocular lens.

I hereby declare that all statements made herein of my own knowledge are true and tha all statements made on information and belief are believed to be true, and further that thes statements were made with the knowledge that willful false statements may jeopardize th validity of the application or any patent issued thereon.

Date: October 28, 2007

GERALD HORN, M.D.